

Classroom Discussion Guide on Ethics and Public Health Emergencies

This guide provides discussion questions and topics based on the Presidential Commission for the Study of Bioethical Issues' report, *Ethics and Ebola: Public Health Planning and Response* (*Ethics and Ebola*), to help instructors integrate ethics discussions into a high school or college science course.¹

Framing Ethics Discussions in a Science Course

Discussion of these ethical issues does not require previous training in philosophy or ethics. This is true for both the students and the instructor. However, it is a good idea to develop a framework for the discussion to make clear to all participants the goals of the exercise.

Potential frameworks include:

1. The class can frame its discussion around two main considerations:
 - a. Is the intervention beneficial in and of itself?
 - b. What are the potential positive or negative consequences of the intervention?
2. The National Institutes of Health Bioethics Curriculum in "Exploring Bioethics" suggests a step-wise framework based on the following questions:
 - a. What is the ethical question?
 - b. What are the relevant facts (scientific and social)?
 - c. Who or what could be affected by the way the question gets resolved?
 - d. What are the relevant ethical considerations?
3. Alternatively, or additionally, the class might engage in a deliberative process to problem solve or generate a policy recommendation. Classroom deliberation encourages students to share competing views and disagree respectfully, with the goal of arriving at consensus about a resolution that seems best given diverse views and perspectives.**

* National Institutes of Health (NIH). (2009). Exploring Bioethics. Retrieved May 13, 2015 from http://science.education.nih.gov/supplements/nih9/bioethics/guide/pdf/teachers_guide.pdf

** McAvoy, P. and D. Hess. (2013). Classroom deliberation in an era of political polarization. *Curriculum Inquiry*, 43(1), 14-47.

The 2014-2015 Ebola Epidemic

The 2014-2015 Ebola epidemic in western Africa illuminated a number of ethical dilemmas that arise in planning for and responding to public health emergencies. Understanding these dilemmas might help us prepare for future public health emergencies.

¹ Presidential Commission for the Study of Bioethical Issues (PCSB). (2015, February). *Ethics and Ebola: Public Health Planning and Response*, Washington, DC: PCSBI. Available at: <http://bioethics.gov/node/4637>.

In February 2015, the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) released *Ethics and Ebola*, which considers ethics preparedness for public health emergency response, focusing on lessons for the future that can be learned from both the U.S. and global response to the 2014-2015 Ebola epidemic. In the brief, the Bioethics Commission considered the ethical use of liberty-restricting public health measures, such as quarantine, and the ethical conduct of clinical research during public health emergencies.

This discussion guide presents two topics that explore ethical challenges for public health emergencies with relevant questions that are well suited for classroom discussion. Instructors should familiarize themselves with *Ethics and Ebola* before initiating classroom discussion. Students should prepare for the discussion by completing the suggested reading ahead of time.

Topic 1: Quarantine and Isolation

For the purposes of discussion, students should download and read the following Bioethics Commission materials (reports are available for download on the Bioethics Commission's website at www.bioethics.gov under "Projects"):

Ethics and Ebola: Public Health Planning and Response, pp. 22-24 ("Overview of Restrictive Public Health Measures") and pp. 26-30 ("Lessons Learned: Past and Present Public Health Use of Restrictive Measures").

Discussion Questions:

1. Kaci Hickox, a U.S. nurse who worked for Doctors Without Borders treating Ebola patients in Sierra Leone, was detained and quarantined upon returning to the United States, despite showing no symptoms of Ebola (individuals are not contagious with Ebola when they do not have symptoms). Were the restrictive measures imposed on Ms. Hickox justified? What are some of the advantages and disadvantages of imposing these measures? What ethical considerations should be taken into account in making decisions about when to impose restrictive measures?

Discussion topics might include:

- *The effectiveness and biological appropriateness of the mandatory quarantine imposed upon Ms. Hickox compared to the self-monitoring measures she engaged in once she was released from quarantine*
- *Whether this mandatory quarantine had an impact on public safety, given the scientific evidence for how Ebola is transmitted*
- *Potential impacts of restrictive measures on healthcare workers involved in public health responses, such as whether and what should be provided to the workers while they are in quarantine and cannot work (reciprocity); whether the measures imposed work to achieve the goal of preventing transmission (proportionality); whether other, less limited*

approaches can achieve the same goal (principle of least infringement); or whether they might have an affect on workers' likelihood of volunteering to help

2. Isolation applies to patients infected with or exhibiting disease symptoms, while quarantine applies to those who have been exposed to a contagious disease (but do not exhibit symptoms). What ethical concerns might you have about how individuals subject to isolation or quarantine are treated, medically or otherwise? In other words, what should we do or not do with regard to quarantining an exposed, but not necessarily infected person? What should we do with regard to an infected and contagious person?

Isolation refers to separation of those infected with or exhibiting symptoms of a communicable disease.

Quarantine refers to separation of persons exposed to but not exhibiting symptoms of a communicable disease.

Discussion topics might include:

- *Statements about quarantine for all exposed individuals as a cautious measure to protect the public*
 - *The importance of relying on accurate scientific evidence about the specific disease to make decisions about restrictive measures policies since diseases differ in how they are transmitted, periods of contagion, how well they are contained by quarantine, and other characteristics (e.g., policies for Ebola might differ from policies for a measles outbreak)*
 - *Discussion about the societal and personal implications of infringing on individuals' liberty*
3. The government of a region immediately affected by an infectious disease epidemic might implement a mandatory quarantine to help contain the spread of disease. Countries that have sent medical personnel and healthcare workers to help fight the epidemic also might consider implementing mandatory restrictive measures for those individuals upon their return home. What information is needed to determine how extensive these restrictive measures should be to protect the public's health? How might the principle of least infringement apply here?

Discussion topics might include:

- *The need to consider reliable scientific evidence specific to the disease and organism in question*
- *Discussion about restrictive measures for individuals or communities and the potential consequences of imposing such measures*
- *Potential alternatives to quarantine (e.g., for healthcare workers during an Ebola outbreak, self-monitoring protocols that involve a lesser degree of infringement on personal liberties for individuals who credible scientific evidence supports are at a lower level of risk—but not no risk—of transmitting the disease)*

Topic 2: Clinical Trials for Vaccines and Treatments

For the purposes of discussion, students should download and read the following Bioethics Commission materials (reports are available for download on the Bioethics Commission's website at www.bioethics.gov under "Projects"):

Ethics and Ebola: Public Health Planning and Response, pp. 32-36 and 38-42 (within "Research Ethics During Public Health Emergencies").

Discussion Questions:

1. Randomized controlled trials are typically considered to be the gold standard of clinical research. However, when research is conducted during an emergency, alternative trial designs might be more appropriate, for example, a design in which every participant receives the experimental treatment or vaccine, in the hope that it will provide some benefit. What ethical considerations are relevant to designing a clinical trial of a treatment or vaccine in the midst of an epidemic?

Discussion topics might include:

- *Whether use of a placebo (in effect, no treatment) is ethically acceptable in research conducted in certain emergency situations, especially when a disease is deadly and there are no known treatments*
- *Difficulty ensuring that potential participants are fully informed about the nature of research, and the potential benefits and risks of participating*
- *Exposing individuals that might be desperate for treatment to research-related risks for uncertain benefit*
- *Challenges to maximizing the ability of a study to generate sufficient amounts of reliable data to further scientific knowledge*

RANDOMIZED CONTROLLED TRIALS

Randomized controlled trials are widely considered to provide the most credible scientific evidence of the safety and efficacy of preventive or therapeutic clinical or public health interventions, although they are not always optimal, feasible, or ethical in every context, and the results can be difficult to extrapolate to nonresearch contexts. The design of randomized controlled trials involves assigning research participants, by chance (randomly), to one of two or more groups, each receiving a different "intervention condition," such as an experimental drug or no experimental drug or placebo (an inactive substance used for comparison that appears as much as possible identical to the experimental intervention) and a set of standard health services. At the end of the study, data from each group are analyzed and compared to answer questions set at the outset of the trial—for example, whether the drug is safe or works to alleviate the symptoms of or cure a particular illness.

2. Patients receiving an experimental treatment during a public health emergency also typically receive supportive care to keep them comfortable and as well as possible. What constitutes supportive care differs by disease. For example, in treating Ebola, supportive care can include pain relief, oral rehydration, intravenous fluids, or more extensive care such as kidney dialysis. Some commentators have argued that patients participating in treatment trials should receive the best possible supportive care, which might be more extensive than what they would receive if they were not participating in the trial. Others have suggested that it is best to provide as much care as is reasonable given the situation (for example, kidney

dialysis might not be feasible if there is no consistent source of electricity). What scientific and ethical factors should be considered when deciding what level of supportive care to provide to research participants during the course of a study?

Discussion topics might include:

- *What level of supportive care is available to patients not participating in the study and will be available to participants after the study is completed*
- *Whether the provision of a higher standard of supportive care might constitute coercion to convince patients to participate in a research trial to obtain better care*
- *Whether the use of extensive supportive care measures, beyond the standard for medical care, might mask the results of a clinical trial and decrease the chances that research results can result in available beneficial interventions*

3. Public health emergencies might provide the only opportunity for researchers to determine whether experimental interventions for certain diseases are effective. What ethical challenges might researchers encounter when faced with this sense of urgency? How might the research be affected as the epidemic wanes? What steps might be taken by researchers and public health officials in advance of an epidemic to facilitate ethical research in an emergency?

Discussion topics might include:

- *Depending on the duration of the epidemic and numbers of participants, a trial might not be able to generate enough data for reliable scientific results about an intervention*
- *Patients might be desperate for treatment and more willing to take on research-related risks for a chance of benefit, even if the chance is low*
- *It might not be possible to obtain fully informed consent for participation in the context of an emergency*
- *The ability to gather useful data likely will diminish as the epidemic wanes*
- *Researchers can prepare research protocols for potential interventions and obtain necessary approvals in advance of a public health emergency so that trials can commence quickly should an emergency occur*